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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,742	09/26/2006	Patrice Marche	128497	6013
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EXAMINER				
LUCAS, ZACHARIAH				
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1648				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/586,742

Applicant(s)

MARCHE ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-23 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15 and 19-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 5/4/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 12-23 are pending in the application.
2. In the prior action, mailed on November 4, 2008, claims 12-22 were pending in the application; with claims 14, 15, and 19-21 withdrawn from consideration; and claims 12, 13, 16-18, and 22 under consideration and rejected.
3. In the Response of May 4, 2009, the Applicant amended claims 12, 14, 18, and 22; and added new claim 23.
4. Claims 12, 13, 16-18, 22, and 23 are under consideration.
5. It is noted that claims 12, 13, and 16-18 read on non-elected inventions. Thus, overcoming the present rejections of these claims would not necessarily render these claims patentable without additional search and examination. See e.g., page 2 of the Restriction requirement mailed on March 17, 2008 (establishing lack of unity between Groups I and II of the application).

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on May 4, 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

7. **(Prior Objection- Maintained)** Claims 12 and 18 were objected to because of the following informalities: the claims identify various proteins and viruses by acronyms without first providing the full name of the protein or virus. The objection is extended to new claim 23.

Applicant asserts that the amendment of the claim to recite the full name of MSRV/HERV-W Env-SU would be cumbersome and unclear. The Examiner does not agree. Rather, the Examiner believes that provision of the full name followed by a parenthetical providing the acronym would clarify the relationship between MSRV/HERV-W Env-SU and the reference to the soluble fraction of MSRV/HERV-W Env later in the claims.

Moreover, it is noted that the application itself indicates on page 1 that the term MSRV is used in the application to encompass the same subject matter as the term MSRV/HERV-W. Thus, there is apparently no need to include the full name of, or even reference to the acronym, HERV-W, in the claims.

The objection is therefore maintained.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(Prior Rejection- Maintained)** Claims 12, 13, and 16-18 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant asserts

that the claim amendments have overcome the rejection. However, the claim still refers to "the pro-inflammatory cascade induced by the activation of MSRV/HERV-W" without providing antecedent basis for the language, while the application indicates that at least 2 such cascades are induced by the protein. It is suggested that the claim be amended to delete reference to the pro-inflammatory cascade as it is not necessary in view of the amendment of the claim to require that the antibody inhibits the interaction between the Env-SU protein comprising SEQ ID NO: 3 and TLR-4.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Maintained in part)** Claims 12, 13, and 16-18 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies for the inhibition of a multiple sclerosis-associated retrovirus (MSRV) induced pro-inflammatory cascade induced by the MSRV Env protein and involving the toll-like receptor 4 protein and methods of using the antibodies for such inhibition, does not reasonably provide enablement for antibodies, or the use of antibodies, against the SU proteins of any MSRV/HERV-W viruses that inhibit any pro-inflammatory cascade induced by any HERV-W viruses. The rejection is withdrawn from claims 12, 13, 17, and 18, but is maintained against claim 16.

The first basis of rejection applied to each of the claims, and had two basis of rejection. First, the claims were rejected as lacking adequate enabling support for antibodies that inhibit the pro-inflammatory responses induced by any HERV-W Env protein. Secondly, the claims were

rejected because the application is not enabling for the making and use of antibodies that inhibit pro-inflammatory responses by other HERV-W Env proteins. The claims have been amended to require the use of antibodies that inhibit the interaction between the soluble fraction of the MSRV/HERV-W Env proteins and TLR4, wherein the soluble fraction of the Env protein comprises SEQ ID NO: 3. In view of the amendment, this portion of the rejection is withdrawn.

The second ground for rejection was that the application does not enable the use of antibodies against MSRV/HERV-W Env-SU antibodies that are capable of inhibiting any inflammatory response that is induced by MSRV/HERV-W activation generally. In view of the amendment of the claims to require that the antibodies specifically inhibit the inflammatory cascade caused by the interaction of MSRV/HERV-W Env-SU with TLR-4, this portion of the rejection is also withdrawn.

The third ground of rejection was indicated to apply to claim 16. The claim was rejected as lacking enabling support for the use of the claimed antibodies to treat any disorder associated with these endogenous viruses. The Applicant provides no specific arguments with respect to this rejection other than the assertion that the claim amendments have overcome the rejection. However, as was indicated in the prior action, there is nothing in the claim to require that the pathology being treated is associated with MSRV/HERV-W Env-SU, the application provides no teachings relating to what pathologies may be associated with other MSRV/HERV-W elements, and there is no indication that the treatment of Env-SU associated pathologies would inherently treat pathologies caused by other MSRV/HERV-W elements. This portion of the rejection is therefore maintained.

12. **(Prior Rejection- Withdrawn)** Claims 12, 13, 16-18 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected on two grounds. First, because there is inadequate descriptive support for antibodies that inhibit any MSRV/HERV-W pro-inflammatory response other than that induced by MSRV Env protein via the TLR4 receptor pathway. Second, there is inadequate descriptive support for any antibodies that inhibit any pro-inflammatory response induced by Env proteins from other members of HERV-W family. In view of the amendments of the claims, the rejection is withdrawn.

13. **(Prior Rejection- Withdrawn)** Claim 22 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reading on material requiring a biological deposit wherein an appropriate deposit meeting the requirements of 37 CFR 1.801- 37 CFR 1.809 has not been made. In view of the amendment of the claim, the rejection is withdrawn.

Conclusion

14. Claims 22 appears allowable over the prior art.
15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/

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Primary Examiner, Art Unit 1648